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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/475,721	12/30/1999	MATTHEW S. REIMINK	1610.1US01	6766
27367	7590	12/14/2006	EXAMINER	
WESTMAN CHAMPLIN & KELLY, P.A.			HON, SOW FUN	
SUITE 1400			ART UNIT	
900 SECOND AVENUE SOUTH			PAPER NUMBER	
MINNEAPOLIS, MN 55402-3319			1772	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/475,721

Applicant(s)

REIMINK ET AL.

Examiner

Sow-Fun Hon

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 27 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-20, 31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-20, 31-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Request for Reconsideration***

1. Applicant's request for reconsideration is fully considered and deemed unpersuasive for the reasons set forth below.

### ***Rejections Repeated***

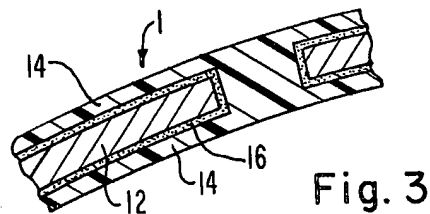
2. The 35 U.S.C. 102(b) and 103(a) rejections of claims 1-3, 5-20, 31-32 over Reul as the primary reference, are repeated for the same reasons previously of record in the Office action dated 04/27/06.

### ***Response to Arguments***

3. Applicant argues that Reul teaches a dipping process to coat the polymer onto the inorganic substrate, and that the dipping process would place a layer having a substantially uniform thickness onto the inorganic substrate that conforms to the general shape of the substrate, and hence would not provide a structure that is shaped differently from the structure of the substrate as claimed, but rather, the polymer coating conforms to the shape of the substrate.

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Applicant is respectfully apprised that the composite structure of Reul in Fig. 3, shown below, discloses a medical device (prosthetic heart valve, column 6, line 29) comprising a composite 1 (valve member 1, column 5, line 41, Fig. 3) wherein the encapsulating polymer 14, shaded with \ (blood compatible synthetic material 14, column 5, lines 41-44), provides a structure that provides the form of the device, and is indeed shaped differently from the inorganic substrate 12, shaded with the reverse hatch // (metal substrate 12, column 5, lines 45-47). Reul teaches that the composite 1 has the shape of a dish (form, valve member 1, column 5, lines 8-10), which is different from the shape of the inorganic substrate 12.



4. Applicant argues that Reul does not disclose a heart valve member that can be bent through a cross-section, [since it is not obvious] that because the valve member has a thickness of 0.3-0.4 mm, it must inherently flex, and that a valve member that flexes would make the valve member less responsive in its opening and closing function which is in direct contrast to the advantages stated of the valve member as stated in Reul, where the valve can react almost instantaneously to the quickly changing pressure gradients inside the heart chamber due to its relatively small moment of inertia which allows very short opening and closing times, since if the valve member is flexed, some of the energy created by the pressure gradient would have to be directed into

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forcing the valve member to flex, and then into moving the valve member about a pivot, thereby decreasing the responsiveness of the valve to the pressure gradient.

Applicant is respectfully apprised that the paragraph in Reul, containing the statements cited by Applicant (column 3, lines 40-50), is initiated by the sentence of "The thickness of the valve member preferably amounts to less than 0.3-0.4 mm.", and followed by "This has the advantage of ...". The composite component is flexible by virtue of its thickness (less than 0.3 – 0.4 mm, column 3, lines 40-42), combined with its composition, which is a thin metal foil substrate and a flexible blood compatible synthetic material body (thin metal substrate, 5, lines 45-46, and coating of blood compatible synthetic material, column 5, lines 41-44, which is flexible, flap made from the same, column 6, lines 44-46, column 4, lines 39-45).

Furthermore, Applicant cites Reul as stating that the valve resembles a natural valve more closely than any other existing artificial heart valve (column 3, lines 40-50). Applicant is respectfully apprised that it is common knowledge that a natural valve is flexible, as evidenced by US 4,888,009 (flexible leaflets of synthetic material somewhat like natural valves, column 1, lines 10-20) and US 5,500,016 (flexible leaflet valves mirror natural heart valves more closely, column 1, lines 23-25).

Therefore, when Reul teaches that the valve member has a thickness of 0.3-0.4 mm, that it has a thin metal foil substrate and a flexible blood compatible synthetic material body, and that it resembles a natural valve more closely than any other existing artificial heart valve, it must inherently flex.

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5. Applicant's arguments against the secondary references, Peitsch, Lenkei and Sumimoto, are directed against the valid use of the primary reference, Reul, and are addressed above.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (571)272-1492. The examiner can normally be reached Monday to Friday from 10:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached at (571)272-1498. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Hon  
Sow-Fun Hon

12/08/06

  
RENA DYE  
SUPERVISORY PATENT EXAMINER